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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,852	09/30/2003	Jacqueline E. Heard	MBI-0022CIP	1145
47550 7590 10/15/2009 MENDEL BIOTECHNOLOGY C/O MOFO SF 425 MARKET STREET SAN FRANCISCO, CA 94105				
EXAMINER				
KRUSE, DAVID H				
ART UNIT		PAPER NUMBER		
1638				
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10/15/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/675,852

Applicant(s)

HEARD ET AL.

Examiner

David H. Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 62-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

STATUS OF THE APPLICATION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 July 2009 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. The Adam Declaration filed 27 July 2009 states that primers for amplifying G482 were known prior to 10 July 1998, oligonucleotides used for designing primers have entry dates of 23 June 1998, and an Excel file has an annotation on 26 April 1998 that cited NCBI Accession No. N97233, which corresponds to the N-terminus of G482 (Declaration ¶3)

This is not found persuasive because none of these show that Applicant conceived of plants comprising a nucleic acid encoding SEQ ID NO:14 and that had a known utility. Further, none of this evidence shows that Applicant even possessed SEQ ID NO:14 at that time - oligonucleotides and a partial sequence are not SEQ ID NO:14 or nucleic acid encoding it. Further, evidence that Applicant did not possess SEQ ID NO:14 is that it is not present in 60/125,814.

For the reasons given above instant claims 62-77 are given the priority date of 30 September 2003, the instant application.

Double Patenting

4. Claims 62-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over pending claim 105 of copending Application No. 11/069,255 for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants arguments are noted (page 7, item 11 of the Remarks), but as the instant claims are not yet deemed allowable the instant rejection is maintained.

5. Claims 62-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over pending claims 68-75 of copending Application No. 10/286,264. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant SEQ ID NO: 4 is identical to SEQ ID NO: 14 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. Claims 62-77 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of making and a transgenic plant made, comprising a recombinant polynucleotide encoding a polypeptide of SEQ ID NO: 4 that exhibits increased germination when grown on high salt or mannitol containing medium

and increased heat tolerance, does not reasonably provide enablement for methods of making and transgenic plants made comprising other recombinant polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 25 February 2009. Applicant's arguments filed 27 July 2009 have been fully considered but they are not persuasive.

Applicants argue that other than the claims directly only to sequences comprising SEQ ID NO: 4, the claims as amended no longer include the functional limitation that the Examiner has asserted that the Applicants have not set forth the relationship between the structure and the function as claimed. Applicants argue that they disclosed numerous closely-related sequences from diverse plant species, where the sequences fall within the scope of the instant claims, and methods for using these sequences to make transgenic plants (page 5, item 7 of the Remarks). These arguments are not found to be persuasive for the reasons of record. It is unclear which of the other asserted species would meet the limitations of the instant claims, i.e. hybridizing to SEQ ID NO: 3. Applicants have argued that the fact that a sequence is expressed in response to an general, as is presently the case, or even a specific environmental influence is not an indication that it will confer tolerance to a specific stress when it is overexpressed. Thus [one] skilled in the art understand that 100s of sequences may be up- or down-regulated in response to an environmental influence. It was recognized in Swindell et al. (2007) "The biological limitations of transcriptomics in elucidating stress

and stress responses." *Heredity* 99: 143-150, that "[c]andidate genes *with a well-supported role in stress-response pathways* provide good prospects for subsequent experimental study" (*emphasis added*; page 149, left column), but "[t]he identification of temperature-related genes [i.e., regulated in response to environmental changes] through microarray analysis represents *only a first step* towards understanding their role in cold- and heat-stress- regulatory *pathways*" (*emphasis added*; page 149, left column). See also Feder et al. (2005) *J. Evol. Biol.* 18: 901-910; "[p]ublished work to date suggests that mRNA abundance typically provides little information on protein activity and fitness and *cannot substitute for detailed functional and ecological analyses of candidate genes*" (*emphasis added*; Abstract). Thus, even today, the skilled artisan would not be inclined to attempt to overexpress each individual sequence determined to respond to an environmental stress to determine if they can be used to produce *tolerance* to a stress (paragraph spanning pages 9-10 of the Remarks in response to the rejection under 35 U.S.C. 103(a)). Whether a plant transcription factor, when overexpressed in a transgenic plant, will give a specific phenotype is highly unpredictable, and as Applicants' have show such a phenotype may be dependent upon which promoter one would use.

Claim Rejections - 35 USC § 103

7. Claims 62-77 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards *et al* (July 1998, Plant Physiology 117: 1015-1022) in view of Harada *et al* (U.S. Patent 6,235,975 B1, filed 24 June 1998) and in further view of Edwards (16 September 1997, Accession No. Y13724, Genbank Sequence, NCBI, National Library

of Medicine, National Institutes of Health, Bethesda, MD). This rejection is repeated for the reason of record as set forth in the last Office action mailed 25 February 2009. Applicant's arguments filed 27 July 2009 have been fully considered but they are not persuasive.

Edwards 1997 is cited as evidence that the AtHAP3b, CCAAT box binding protein as publicly disclosed on 16 September 1997.

Applicants argue that they conceived of the present invention prior to the publication of the Edwards reference, and worked diligently to reduce the claimed invention to practice. In priority application 60/125,814 on 03/23/99. Applicants argue that they disclosed transgenic plants comprising the same sequence that Edwards taught, and Applicants reduced the invention to practice before one year after the Edwards publication had elapsed. Applicants argue that the attached declaration under 37 CFR 1.131 of Dr. Luc Adam, showing that Applicants designed primers for a G482-overexpressing plant at least as early as December 3, 1997, and continued to design primers for this sequence up to and after July 10, 1998, the earliest date the Edward publication may have been available to the public (this date is indicated in the attached email from Ms. Nancy Winchester, Director of Publications, of the *American Society of Plant Biologists*, publisher of *Plant Physiology*; Ms. Winchester has consented to the use of this email for this and related responses). Applicants argue that the file creation dates of two of the files referred to in the Adam declaration can be seen in the attached file "G481G482ArchivalFiles.pdf". The file "12000 annotated ESTs.xls" was created on April 26, 1998, and the file "la.xls" was created on July 8, 1998. Applicants argue that

they conceived of the invention prior to the effective date of the reference, and said conception was coupled with due diligence from prior to said date to the filing of the 60/125,814 application on 03/23/99 (page 6, 3rd paragraph of the Remarks). These arguments are not found to be persuasive for the reasons given *supra* under "Priority", in addition the Examiner has made of record the public availability of the Y13724 Accession teaching the AtHAP3b CCAAT box binding protein.

Applicant urges that carrying out research to determine a real-world use is not a substantial utility, which is required for an obviousness rejection (page 7 of the Remarks).

This is not found persuasive. In *In re Sterniski* "those in the art at the time appellant's invention was made may be unaware of *any* significant properties or uses possessed by the prior art compounds" (emphasis in the decision, pg 345). In the instant case, a role in osmotic stress would be a significant property or use. Thus, the fact patterns in the instant case differ from those in *In re Sterniski*. Further, *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), pg 1397, made clear that "obvious to try" is motivation to combine elements in the prior art. In the instant case, there was at least one species that would have been obvious to try using the guidance of Edwards 1998, that renders obvious the instantly claimed genus.

Conclusion

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
13 October 2009